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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,109	06/21/2001	Anita Diu-Hercend	146 1353	3121

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EXAMINER	
LEFFERS JR, GERALD G	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/674,109	DIU-HERCEND ET AL.	
	Examiner	Art Unit	
	Gerald G Leffers Jr., PhD	1636	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-28* is/are pending in the application.

4a) Of the above claim(s) *14 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13,15,16 and 18-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the invention directed to Group 239 (claims 13, 15-16, 18-28 directed to *in vitro* methods of screening for antimycotic substances using the gene product encoded by YDR181c) in the paper filed 8/26/03. Arguments against the restriction were also presented in the response filed 5/27/03. The traversal is on the ground(s) that (1) there is the same general inventive concept present in each of the groups (i.e. using a method for screening of an anti-mycotic functionally similar mycete gene of a Markush group thereof and all of the steps are the same with only the gene being different, and (2) the examiner has apparently "changed his mind" and required an election of species. This is not found persuasive because of the following reasons.

First, the arguments ignore the reasons given for restriction in the original restriction mailed 4/28/03 (Paper No. 12), namely that the special technical feature for each of the methods is dependent upon the structural/functional characteristics of the particular gene or gene product used in the assay. Assertions that the examiner *ever* made a requirement for species election are inaccurate. From the beginning the examiner has grouped methods comprising each of the different products (e.g. nucleic acid or proteins) in different groups for the particular gene or gene sequence (that's why there were 360 different *groups*). At no point did the examiner present, for example, a "Group III" or indicate in any other way that there is an elections of species.

Claims 13-28 are pending in the instant application. All of the remaining groups directed to other claims and/or different products (i.e. genes or gene products other than the YDR180c

gene product) and/or different methods (i.e. *in vivo* methods) have been withdrawn as being nonelected inventions.

The requirement is still deemed proper and is therefore made FINAL.

Specification

It is not clear that applicants have provided a sequence corresponding to YDR181c or its gene product (e.g. its not clear that the sequences are present in the sequence listing comprising 180 different sequences). These sequences are essential information required for practicing the claimed invention. If applicant has attempted to merely incorporate these sequences by reference, it is improper. The incorporation of essential material in the specification by reference to a foreign application or foreign patent, or to a publication is improper. If this is the case, Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See In re Hawkins, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); In re Hawkins, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and In re Hawkins, 486 F.2d 577, 179 USPQ 167 (CCPA 1973). If the essential subject matter is in fact in the specification, applicant need only indicate the appropriate sequence identifier (i.e. SEQ ID NO).

Claim Objections

Claims 13, 15-16, 18-28 are objected to because of the following informalities: each of the claims remains directed to nonelected embodiments. Applicants have elected methods directed to screening for antimycotics using the YDR181c gene product *in vitro*. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13, 15-16, 18-28 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The invention is complex, involving the use of a specific gene product encoded by YDR181c in *in vitro* assays to identify compounds that are antimycotic. The success of such methods depends on the role the YDR181c protein plays in the cell.

Breadth of the claims: The claims encompass any assays that can be done *in vitro* using the YDR181c protein so long as the compounds identified can act as an "antimycotic compound". A reasonable interpretation of the term is that the compound is fungicidal, or at least inhibitory of cell growth under some condition.

Guidance of the specification/The existence of working examples: The specification has only prophetic teachings as to the possible role in the yeast life cycle and a perfunctory statement that the gene products of the invention are "essential" to the cell (page 25, lines 27-36). No specific data for the YDR180c gene product is given.

State of the art/Predictability of the art: Post-filing art indicates that the role of the YDR180c gene product in the yeast cell cycle was poorly understood at the time of filing. Xu et al (Xu et al. Genetics, September 1999, Vol. 153, pages 13-23.) teach that YDR180c corresponds to a gene termed SAS4 that is involved in suppressing mating phenotypes in S. cerevisiae (e.g. Abstract; page 17, columns 1-2). In particular, the specification teaches that null mutations in SAS4 do not result in any detectable change in cell growth.

The amount of experimentation necessary: Given the combination of factors outlined above, it would take undue, unpredictable experimentation to construct and use the claimed methods to identify compounds that are antimycotic. This is particularly true in light of a lack of a defined role for the YDR180c gene product at the time of filing, and the subsequent finding that null mutants in the YDR180c gene are viable. For all of these reasons, the instant specification is not found to be enabling for the claimed methods of identifying an antimycotic compound.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13, 15-16, 18-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13, 15-16, 18-28 are vague and indefinite in that the metes and bounds of the term "antimycotic" are unclear, particularly in the absence of an explicit definition in the specification or claims. Must the tested compound be lethal in order to be "antimycotic"? If the compound need only be inhibitory, then how inhibitory and in what manner must it be in order to satisfy the claim limitation?

Claims 13, 20-21 are vague and indefinite in that the metes and bounds of the term "functionally similar mycete gene" are unclear. How similar does the gene or gene product have to be in order to satisfy the claim limitation? Is similarity determined by some function, or sequence identity, or both? Claims 22-24 at least specify that the functionally similar protein is identified by its capability to complement the reference gene product *in vivo*.

Claims 27-28 are vague and indefinite in that there is no clear and positive prior antecedent basis for the phrase "the essential genes of S. cerevisiae" in claim 13, upon which each of these claims is dependent.

Claims 13, 16, 18-21, 25, 27 provide for the use of the YDR181c gene product, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 13, 16, 18-21, 25, 27 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr., PhD
GERRY LEFFERS Primary Examiner
PRIMARY EXAMINER Art Unit 1636

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